

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Girtton, et al.

Examiner: Patterson, Marc A.

Serial No.: 10/002,521

Group Art Unit: 1772

Filed: November 1, 2001

Docket: 760-35 CIP/RCE IV

Confirmation No.: 6660

Dated: May 27, 2008

For: NON-EXPANDED POROUS
POLYTETRAFLUOROETHYLENE
(PTFE) PRODUCTS AND METHODS
OF MANUFACTURE

Commissioner for Patents
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Dated: May 27, 2008

Signature: Marcy Mancuso



STATEMENT IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In support of the concurrently-filed Notice of Appeal and Pre-Appeal Brief Request for Review, please reconsider the patentability of the claims of the above-identified application in view of the following Remarks. A petition for a two-month extension of time is being filed concurrently herewith. Accordingly, this response is timely filed on May 27, 2008, with a two-month extension of time.

REMARKS

Claims 2-3, 21, 22, 24 and 27 remain in this application. Appellants respectfully request reconsideration in view of the following remarks.

Claims 24 and 27 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Statutory Invention Registration No. H1978 H to Freiburger et al. (hereinafter "Freiburger"). Claims 3 and 21-22 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Freiburger in view of U.S. Patent No. 6,190,590 to Randall et al. (hereinafter "Randall"). Appellants respectfully traverse the rejection on the grounds that the references fail to teach or suggest Appellants' claims 2-3, 21, 22, 24 and 27, and thus, fail to make out a *prima facie* case of obviousness.

This Statement specifically addresses the Freiburger and Randall references as cited in the rejection of the only independent claims currently pending, i.e. claims 3 and 24.

Claims 3 and 24 relate to a PTFE extrudate that includes "an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure" and "a solid particulate polymeric component which is incompatible with said non-expanded PTFE resin." Claim 24 uses closed "consisting essentially" language. The polymeric component includes discrete domains distributed throughout the non-expanded PTFE resin that are extracted to create pores in the PTFE resin and thereby permit tissue ingrowth.

1. Freiburger is Nonanalogous Art

Freiburger is nonanalogous art because it is in a different field of art and is directed to an entirely different problem than the present invention. Freiburger relates to monolithic films that have controlled breathability and include high water vapor transmission rate (hereinafter "WVTR") regions and low WVTR regions. The monolithic films of Freiburger are utilized to create absorbent undergarment or diaper training pants. As such, Freiburger bears no relevance on the prosthesis field of art, nor the inventors' concerns in achieving a porous PTFE material to use in a variety of medical device products without requiring expansion to produce porosity. One of ordinary skill in the medical implantation art would not logically look to the field of absorbent undergarments for guidance with respect to non-expanded porous PTFE extrudates to be used as implantable grafts and stent-products.

Freiburger's absorbable diaper is clearly outside the inventors' field of endeavor, i.e. fluid-tight implantable prostheses having sufficient porosity for tissue ingrowth. Freiburger seeks to solve the breathability problems associated with absorbent garments, which is an entirely different and unrelated problem than the problems addressed by the present invention, i.e. forming a porous PTFE graft without using the standard heat stretching, which creates a node and fibril structure.

a. Appellants' problem was to obtain a porous PTFE material for use in a medical device without the cost and difficulty associated with conventional expanded PTFE

Appellants were concerned with producing a porous PTFE material to be used in a medical device, without having to partake in the expensive costs and technical difficulties associated with the expanding techniques used for making the conventional ePTFE.

The overall purpose of the present invention is to create a porous medical device that can be implanted in the body and permit tissue ingrowth without relying on the conventional stretching techniques. The tissue ingrowth process is partially dependent on the ability of blood cells to enter the pores and providing a porous non-expanded PTFE, suitable for implantation in the body. The technical problems associated with the invention do not relate to those associated with absorbent diapers. The present invention overcame these problems by distributing an extractable polymer throughout an IPN and PTFE matrix, then exposing the polymer to a sufficient degradation temperature or dissolving medium to extract it. The resultant product includes pores that permit blood cell penetration, while maintaining a fluid-tight graft.

b. Freiburger's problem was to obtain a diaper with a breathable barrier

Freiburger is directed to a monolithic film, which is defined as "non-porous". (Freiburger, col. 3, ll. 10-11). The film has "passages with cross-sectional sizes on a molecular scale formed by a polymerization process." (Freiburger, col. 3, ll. 13-14). The purpose of these passages is so water or liquids can diffuse through the monolithic film "as a result of a concentration gradient" and are re-evaporated into the air. (Freiburger, col. 6, ll. 60-col. 7, ll. 7). However, as stated in Freiburger's specification, "monolithic film provides an absolute barrier to liquids, bacteria, and viruses as no pores are present in the film...no liquid flow is possible unless the film ruptures." (Freiburger, col. 7, ll. 17-30) (emphasis added). Freiburger even specifically states that "holes are never intentionally introduced into the film." (col. 7, l. 52).

Blood cells are typically approximately 6-8 microns in diameter. Typically, bacterial molecules are in the size range of 0.5-5 microns and typical viruses are in the size range of 10-30 nm, both ranges being below the size that would permit red blood cell penetration, a necessary precondition to tissue ingrowth. As Freiburger provides "an absolute barrier" to bacteria and viruses, it clearly teaches away from a pore size that would encourage tissue ingrowth.

Furthermore, the Examiner has misapplied the reference. The Examiner claims that Freiburger discloses an IPN with discrete extractable domains that are extractable. However, nowhere in Freiburger is extractability. Freiburger describes "a polymer/polymer composite combining polydimethyl siloxane and polytetrafluoroethylene in an interpenetrating polymer network." This

combination is the final product of Freiburger and is necessary to achieve her purpose. This is in contrast to the present invention, where a polymer is extracted to create a porous PTFE structure that permits tissue ingrowth. The focus of the present invention is to distribute pores or voids throughout the PTFE matrix by using an extractable polymeric component. Without the extractable polymeric component, the IPN would not be porous and would not permit tissue ingrowth. In stark contrast, Freiburger explicitly states that holes are undesirable and "never intentionally introduced into the film." (Freiburger, col. 7, l. 52). Freiburger does not remove the siloxane from the matrix because that would be contrary to the intent of the invention.

The Examiner alleges that one of ordinary skill in the art would have utilized the teachings of Freiburger to modify the pore size in order to have pores that permit tissue ingrowth. Appellants respectfully submit that such an assertion is incorrect. Not only does Freiburger's final product related to a wholly different material than the presently claimed invention, the monolithic film discussed in Freiburger acts as a complete barrier to bacteria and viruses. There would be no reason one of ordinary skill in the art would look to Freiburger's non-porous monolithic barrier film, to create a porous PTFE extrudate for implantation in the body, nor could there appear to be any expectation of success in so doing.

The Examiner acknowledges that Freiburger fails to disclose a vascular graft, but alleges that it would have been obvious to combine the teachings of Randall with Freiburger to provide a vascular graft. (See Office Action of 12/27/2007, at pages 3-4)

Even if, *arguendo*, Freiburger is found to be analogous art, combining Freiburger and Randall not only does not arrive at the present invention, the combination of references is improper. As stated in detail above, Freiburger is directed to an absorbent garment. Randall is directed towards a graft that is made of microporous expanded polytetrafluoroethylene (ePTFE). One of ordinary skill in the art would not look to an absorbent garment, to be worn outside of the body and an ePTFE graft to create the presently claimed invention.

Not only is there no motivation to combine Freiburger and Randall, there is incentive not to combine them. When Freiburger is considered for its whole teaching, it would provide no direction toward solving Appellants' problem. Randall utilizes ePTFE, which, as stated above, is the expense and

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difficulty Appellants sought to avoid. One of skill in the art would have no incentive to combine an absorbent diaper with an ePTFE graft to solve the problems associated with ePTFE grafts.

As such, Appellants respectfully submit that independent claims 3 and 24, and thus all claims that depend therefrom, are patentable over Freiburger and Randall, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested. Having responded in full to the present Office Action, it is respectfully submitted that the application is in condition for allowance. Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,

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